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Excess treatment costs

Guidance on the national management model for England

Version 2, March 2022

Changes to version 1 are highlighted in yellow

Contents

1. Background

1.1 Introduction

This document provides guidance for the process of managing excess treatment costs (ETCs) for research falling within the responsibilities of NHS commissioners in England. It has been jointly agreed by NHS England and NHS Improvement (NHSE&I) and the Department of Health and Social Care (DHSC). It has been written with feedback from stakeholders including the National Institute for Health Research (NIHR) and the Health Research Authority (HRA).

Separate arrangements are in operation for ETCs in research for public health interventions that are not commissioned by NHS commissioners in England. Guidance on this process can be found here.

1.2 Definition of ETCs

A research study may result in care that differs from standard treatment in the NHS or is delivered in a different location. The associated NHS treatment costs may be less than or greater than the cost of standard treatment. If greater, the difference between the NHS treatment costs and the cost of the standard treatment is referred to as the NHS excess treatment costs (ETCs).

1.3 A national model to manage ETCs

In November 2017, NHS England, NIHR, DHSC and HRA consulted on proposals to better manage ETCs in the NHS in England. Taking into consideration the responses to that consultation, NHS England and partners outlined a model for managing ETCs[1] and this model was implemented on 1 October 2018.

For services NHSE&I commission directly (eg specialised services), the national arrangements apply to studies that received confirmation of research funding on or

[1] NHS England's response to the public consultation: *'Supporting Research in the NHS: A consultation covering changes to simplify arrangements for research in the NHS and associated changes to the terms of the NHS Standard Contract'.* https://www.england.nhs.uk/commissioning/supporting-commissioners/research/supporting-and-applying-research-in-the-nhs/

after 1 October 2018. ETC decisions for studies funded prior to this date will continue to be processed following the pre 1 October 2018 arrangements, even if the study has continued beyond that date. For these pre 1 October 2018 studies, the ETC approval decision sits with the relevant local/regional specialised commissioning team(s), as the budget holders for the associated clinical activity commissioned from local NHS trusts and other commissioned providers.

This guidance should be read in conjunction with the ETC information on the NIHR website. The process flow chart for non-commercial studies that have ETCs can be viewed here. Additional supporting information around the steps outlined within the process flow chart can be viewed here.

1.4 Eligibility for ETC funding and ETC payments

Eligibility for ETC funding

For eligible non-commercial studies, NHSE&I and clinical commissioning groups (CCGs) have responsibility – via the Government's mandate to us – to meet the costs of ETCs through normal commissioning arrangements.

Historically, Health Service Guidance (HSG) (97) 32 set out the responsibilities for meeting patient care costs, including ETCs, associated with research and development in the NHS. This included guidance for eligibility for ETC funding based around organisations that award research funding.

The DHSC Eligibility Criteria for NIHR Clinical Research Network (CRN) Support policy sets out the criteria for eligibility of studies for NIHR CRN support. The criteria in this eligibility policy are broader than those defined in HSG (97) 32, such that NIHR partner organisations which may not be UK registered charities may be eligible for CRN support, but not ETC funding.

In addition, the NIHR CRN eligibility policy also provides for studies, classified as 'non-commercial', which are initiated by non-commercial investigators with research funding provided by commercial organisations, referred to as investigator-initiated, commercial collaborative studies.

With DHSC, NHSE&I are currently reviewing these CRN eligibility criteria and the classification of investigator-initiated studies to provide clarity on which studies are eligible for automatic ETC reimbursement (and CRN support). This work is ongoing

and will take time to ensure all stakeholders have had the opportunity to contribute. In the interim, we will continue with the current practice in relation to reimbursement of ETCs.

This means that:

1. As is current practice, ETCs for studies that are included in the NIHR CRN Portfolio, where CCGs are the responsible commissioner, will continue to be automatically reimbursed (subject to provider thresholds and high cost study review).

2. As is current practice, where NHSE&I are the responsible commissioner – eg specialised commissioning – the ETCs for the following studies will continue to be automatically reimbursed:
    - Studies in which the research costs (as defined in HSG (97) 32) are fully funded by:
        - NIHR
        - UK Research and Innovation
        - another UK government department
        - an Association of Medical Research Charities (AMRC) member
        - fully funded in combination by one or more the above funders
    - majority funded by one or more of the above funders
    - fully funded by the European Union (EU); this provision will be reviewed now the UK is no longer part of the EU.

3. As is current practice, where NHSE&I are the responsible commissioner, NHSE&I will exercise discretion and review the study before agreeing to fund ETCs for the following studies:
    - fully or part funded by an NIHR partner which is not a full AMRC member
    - any investigator-initiated, commercial-collaborative studies
    - fully or part funded by overseas (ie non-UK) governments, overseas charities or other overseas institutions.

Eligibility for ETC payments

Providers sites incurring ETCs should be delivering routine NHS services or patient care services as part of specific and time-limited programes.

2. ETC attribution, costing and validation

Full guidance on the Schedule of Events Cost Attribution Template (SoECAT) and accompanying guidance for completion can be accessed from the NIHR website.

2.1 Overview of the process

Attribution

The SoECAT for clinical research is a spreadsheet-based application whose purpose is to capture the different activities associated with clinical research at the research site level and attribute them accordingly as ‘research activities’, ‘support activities’, or ‘treatment activities’, in line with the national guidance document 'Attributing the Costs of Health and Social Care Research and Development' (AcoRD).[2]

Guidance on when a SoECAT is required can be found in the full SoECAT guidance referred to above. A SoECAT is required by NIHR and NIHR non-commercial partner research funders where the call for applications for funding relates to studies that may involve participants under an NHS or health and social care duty of care.

A SoECAT should be completed for the research cost funding application for any non-commercial or investigator-led commercial collaborative study intended for the NIHR CRN Portfolio. This applies even where the funder is not an NIHR non-commercial partner funder (ie where an application for adoption of the study to the portfolio will be required).

Some funding calls may attract both applications for studies that require SoECAT completion and applications for studies where SoECAT completion is unnecessary.

[2] https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

In these circumstances the default position is that the SoECAT should be submitted for all applications, but where completion is not needed this should be documented within the SoECAT submission, as required by the SoECAT guidance, and ratified by AcoRD specialist authorisation.

SoECATs should also be completed for applications for research awards that fund a programme of activity such as NIHR programme grants for applied research.

Information on the eligibility criteria for NIHR Clinical Research Network Support can be found here.

Costing

The SoECAT includes functionality that calculates a proposed average ETC per participant value for studies within the English ETC management model. The SoECAT is a cost attribution tool and is not intended to be used as a tool to derive true site level costs.

Further information on this distinction is provided in the SoECAT guidance.

Commissioner triage

Once an ETC value has been calculated and the SoECAT authorised by the NIHR Local Clinical Research Network (LCRN) AcoRD specialist, it should be submitted with the application for research funding in accordance with the instructions for that funding call.

Once research funding is awarded in principle, the validated SoECAT is passed onto a 'triage' process, via the NIHR Clinical Research Network Co-ordinating Centre (CRNCC) (see process chart here, with additional supporting information here). The triage process determines the 'responsible commissioner' for the treatment/care in the study by considering the submitted SoECAT, protocol, research funding award and other supporting documentation.

Confirmation of ETC value

Following the triage decision:

- For studies where CCGs are the sole or primary responsible commissioners for funding ETCs, the sponsor will be responsible for providing CRNCC with information to ensure the appropriate sites are reimbursed for their ETCs. The CRNCC will then – using the SoECAT and

information provided by the sponsor – provide to the sponsor a breakdown of the costs that will be attributed to the sites. The ETC payments will be based on recruitment data and the average ETC per participant value.

- For studies where CCGs are the sole or primary responsible commissioners for funding ETCs, the ETC per participant value generated by the SoECAT will be used to calculate the ETC payments payable to providers.

- For studies where NHSE&I specialised commissioning is the sole or primary responsible commissioner, an additional financial assurance process is required to determine the net ETC funding that providers will require. This is to ensure there is no duplication of payments for activity likely to already be chargeable under existing NHS contracts. We will provide additional support and guidance to the applicant and their finance team where needed to complete the assurance process.

- For studies involving services commissioned by other NHSE&I commissioners and for public health studies commissioned by local authorities, where there is an equivalent excess intervention cost, the ETC per participant value generated by the SoECAT will also be used to help inform the final agreed value. For guidance on managing ETCs for research into public health interventions commissioned by non-NHS organisations in England, read the following document: *Researcher guidance for public health ETCs*.

2.2 Prior to applying for research funding for eligible studies that will incur ETCs

To ensure the attribution of study activities complies with the DHSC AcORD Guidance, study teams are actively encouraged to contact their LCRN for support from a designated AcoRD specialist to complete the SoECAT.

The AcoRD specialist in the Lead LCRN (meaning the LCRN that takes overall responsibility for the study within the NIHR CRN) must authorise the SoECAT prior to submission of the funding application for it to be validated.

Researchers should contact their LCRN as early as possible to request attribution support. The absolute minimum time required to ensure sign off by the submission date is 20 working days prior to the submission of a funding application.

A maximum of 10 additional working days (prior to funding submission) from confirmation of AcoRD specialist reviewer is suggested to provide leeway for any amendments or escalations to be resolved.

Should any significant disagreements on attribution arise between researchers/sponsors and AcoRD specialists, the CRN attribution support and review standard operating procedure will be applied to escalate these cases.

2.3 When research funding has been agreed/awarded

When a researcher receives confirmation that research funding is awarded, the research team must inform the lead LCRN's AcoRD specialist for the study, as denoted on the front of the authorised SoECAT form.

If funding has been awarded dependent on changes to the study design, the team must inform the AcoRD specialist so that any subsequent changes to the attribution of study activities are reflected, if appropriate, in an amended and authorised SoECAT.

Where the study will incur ETCs, this contact will trigger the process followed by AcoRD specialists to determine:

a) the responsible commissioner for ETCs (ie the Commissioner Triage process described above)

b) whether the study is categorised as having 'high cost' ETCs (see Section 7).

The AcoRD specialist will inform the research team of the outcome and next steps (see process chart here with additional supporting information here).

2.4 IRAS submission for HRA and HCRW approval and application for CRN support

Where a SoECAT was submitted in application for research cost funding, the AcoRD specialist authorised SoECAT (authorised to reflect change requests made by the funder, or other changes, if necessary) should be submitted as part of the

Integrated Research Application System (IRAS) form document set when applying for research approvals, and subsequently as part of an application for NIHR CRN support.

If the study includes more than one type of site, the authorised SoECAT should be duplicated by the study sponsor under the direction of the HRA. This should reflect the number of site types, and activities removed from each that are not relevant to that site type.

The SoECAT should also be included in the UK local information pack shared by the sponsor or their authorised delegate with their NHS research sites, to support those sites in making arrangements to deliver the study.

Full details are provided in the SoECAT guidance.

3. ETC payment mechanisms

3.1 Payment principles

The standard model is that ETC payments are calculated using study participant recruitment data multiplied by the final approved average ETC per participant value. This value reflects the net costs of drug purchase, staff training to deliver the experimental intervention, and so on.

The ETC funding system does not allow for ETCs incurred in advance of participant recruitment – so called 'up-front' costs – to be paid.

Researchers should manage and plan studies appropriately to ensure that costs are not incurred unnecessarily. This includes using robust recruitment estimates to feed into per participant ETC calculations. Purchasing drugs in batches can also help to minimise potential waste. Researchers are expected to minimise the cost of drugs and devices to the NHS by seeking discounts from manufacturers where possible.

Subject to preserving the integrity and independence of the study, the use of lower cost generic/biosimilar options should be considered. Where costs relate to staff recruitment to deliver an intervention, the number of staff recruited and/or trained

should be proportionate to the expected participant recruitment to recover these costs.

The NIHR CRNCC acts on NHSE&I's behalf in managing study information and calculating ETC payments for studies where CCGs are the responsible commissioner.

It is vital that providers ensure study recruitment data in the NIHR CRN Central Portfolio Management System (CPMS) is accurate and up to date within the specified NIHR data cut deadline dates. This will ensure providers are reimbursed at the correct rate.

All study recruitment and site data must undergo quality assurance within CRN before these data are approved for use in ETC payment calculations. Recruitment data recorded in the NIHR CRN CPMS as 'provisional' data – ie data that has not been confirmed – will be excluded from the ETC payments.

3.2 Payments from LCRNs on behalf of CCGs

Using data on the NIHR CRN CPMS, on a quarterly basis ETC reimbursement payments are calculated and payment schedules produced setting out the amounts to be paid to each site for each study. Payments are calculated using the average ETC per participant value agreed for each study and the provider level recruitment data for that study, recorded and confirmed in CPMS. That is to say: payments are made on a per participant basis based on recruitment, quarterly in arrears. Payments are subject to the provider threshold applied to an organisation (see section 5).

Where CCGs are the responsible commissioner, ETC payments are made to providers by the LCRN host organisation. For these studies, information on cumulative ETCs relating to recruitment is available through the NIHR Open Data Platform (ODP).

This enables providers to visualise the data, monitor their ETC spend against the threshold and ETCs due for reimbursement once the threshold has been reached. LCRN hosts do not require the submission of invoices to generate a payment.

3.3 Payments from NHS England and NHS Improvement specialised commissioning

NHSE&I will make payments direct to providers on a quarterly basis, in arrears, through normal contractual arrangements. This will be based on confirmed participant recruitment data captured in CPMS (number of participants recruited in that quarter multiplied by the payable average ETC payment agreed following the additional financial assurance process).

As NHSE&I already have a system in place to make payments to commissioned providers, ETC payments for NHSE&I commissioned studies are simply added to the relevant quarterly payment run for each commissioned provider. Providers can monitor recruitment data on ODP for studies where NHSE&I are the responsible commissioner.

4. Provider thresholds

For all providers other than primary care providers, an annual threshold is applied for ETCs. Primary care services (and therefore providers) are defined as general practice services, general dental services, community pharmacy services and optometry services. These providers are exempt from the provider threshold.

Where thresholds are applicable (see Table 2 below), in each financial year providers are expected to absorb ETCs incurred up to the value of their individual threshold. Once the threshold value has been reached, any further ETCs incurred by the provider will then be reimbursed.

For the avoidance of doubt, the threshold is only relevant to ETCs for CCG-commissioned studies: ETCs for studies for which NHSE&I are the responsible commissioner are exempt from the threshold arrangement.

The value of the annual NHS provider threshold is taken as a percentage of total operating income for the provider or a set amount, whichever is the greater. NHSE&I review the thresholds on an annual basis. NHSE&I communicate the value of the provider threshold to NHS trusts at the beginning of the financial year. These can also be viewed in the NIHR ODP.

In considering thresholds, NHSE&I have taken into account that many studies generate excess treatment savings (which providers can retain as a result of participating in research). This is in addition to the time and costs eliminated by not needing to negotiate ETCs locally for relatively small sums, where the administrative costs to providers and commissioners related to agreeing payments outweigh the cost of the ETC itself.

If services are subcontracted by an NHS provider that has been allocated a threshold, the respective providers are expected to agree how the ETCs will be funded within the limits of the threshold. It is expected that where payments are being passed between organisations, the relevant parties will have valid contractual arrangements. In addition, it is expected that the provider transferring funds will have carried out due diligence for the quality of care delivered by the provider receiving ETC payments.

For independent sector healthcare providers (ISHPs), companies that qualify as small companies[3] have their thresholds set to zero. For all other ISHPs (excluding residential care homes and nursing homes), NHSE&I set a fixed threshold prior to each financial year. The value of the threshold can be obtained from NIHR ETC helpdesk (ETC.Helpdesk@nihr.ac.uk).

Table 1: The annual thresholds to be applied to different types of providers incurring ETCs

Organisation	Threshold value
NHS trusts	Predetermined prior to the financial year (a % of total operating income)
Primary care • general practice services • general dental services • community pharmacy services • optometry services	No threshold

[3] https://www.legislation.gov.uk/ukpga/2006/46/part/15/chapter/1/crossheading/companies-subject-to-the-small-companies-regime

Independent sector healthcare providers (ISHPs)/companies (not including charities, hospices, residential care homes and nursing homes)	Fixed threshold predetermined prior to the financial year
Charities and hospices	No threshold**
Residential care homes and nursing homes	No threshold**
Higher education institutes (HEIs)	No threshold

HEI, as a study sponsor, may act as a payment co-ordinating organisation distributing ETC payments to primary care providers. This is because, in this instance, no thresholds will be applied; primary care providers do not have thresholds applied to them. It is expected that HEI would not be undertaking this role to research providers where thresholds are applied.

** This will be monitored and may change in future.

5. Primary care minimum cumulative payments

A minimum payment trigger is applied for ETCs incurred by primary care providers. This is not a threshold under which primary care providers must absorb ETCs but a value for cumulative CCG ETCs that must be reached before CCG ETCs are automatically paid. This has been introduced to prevent the cost of processing ETC payments outweighing the actual cost of the ETCs.

The ETC value will be paid each quarter once the minimum payment trigger is reached.

Any ETCs that were not paid because the payment trigger had not been reached will be paid in full at year end.

6. Studies with high cost ETCs

The ETC model implemented in October 2018 includes a high cost threshold that has been introduced to enable NHSE&I and DHSC to review studies with high cost ETCs and assure the value of the study to the NHS prior to the agreement of ETCs.

6.1 The threshold

A high cost ETC threshold applies to all studies eligible for ETC funding. The current value of the high cost threshold can be viewed on the NIHR ETC webpage. The threshold applies to total ETCs incurred across the United Kingdom.

Funders have been asked to notify NHSE&I and DHSC when a study with ETCs above the high cost threshold is awarded funding. This identification process will run in parallel to the AcoRD specialist identifying these studies, ensuring all studies that require a review are identified as soon as possible.

6.2 Criteria for assessment of clinical alignment

For all studies with ETCs that exceed the high cost threshold an assessment of clinical alignment, and therefore value to the NHS, will be conducted prior to agreement to fund ETCs.

The following criteria will be used to make an assessment of clinical alignment:

a) Is the level of proposed ETC investment proportionate to the potential future patient benefit(s) in terms of clinical and/or patient outcomes? Would the treatment have a reasonable chance of being adopted into future routine NHS care given its expected relative benefit and cost?

b) Does the study replicate research already undertaken/due for publication and therefore offer no or limited additional value to patients and the NHS in terms of understanding the evidence base and developing future clinical commissioning policy?

c) Is the study in an important clinical area but misaligned with NHSE&I's and/or DHSC's understanding of the treatment regime or patient cohort that might be best prioritised for further study?

d) Is the study design satisfactory; for example, is it sufficient to produce findings likely to be of material use in future clinical commissioning policy determination, have opportunities been taken to explore the use of the best value product (eg biosimilars), is there evidence that the recruitment target and timetable is realistic?

6.3 Assessment of clinical alignment

For studies where the ETCs mainly relate to CCG commissioned services an assessment of clinical alignment will be undertaken on a case by case basis by:

a) The relevant NHSE&I national clinical director (NCD) or nominated clinical expert

b) The Innovation, Research and Life Sciences (IRLS) director or deputy director for research from NHSE&I; and

c) Relevant clinical expert designated by DHSC.

For high cost ETC studies where the ETCs are mainly related to services NHSE&I have directly commissioned (such as a specialised service), an assessment of clinical alignment will be undertaken on a case-by-case basis by:

a) The relevant regional medical director or nominated clinical expert; and

b) The clinical lead or chair of the relevant programme of care or clinical programme.

The possible outcomes of the assessment are:

1. Clinical alignment agreed and therefore ETC funding is agreed.

2. Clinical alignment is in question. There will be discussion and negotiation with the lead investigator/sponsor and funder to attempt to agree any changes to the protocol/methodology that will enable alignment to be agreed:
   a) Agreement to changes to ensure clinical alignment and ETCs funding is agreed.
   b) Following discussion and negotiation agreement to amend the study to bring into clinical alignment is not possible. ETCs will not be funded.

NHSE&I will notify funders of the decision directly.

7. Further information

Further information is available on the ETC web pages on the NIHR website. For further ETC general or study specific queries please contact etc.helpdesk@nihr.ac.uk.

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